IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: METOPROLOL SUCCINATE END-PAYOR ANTITRUST LITIGATION	)	C. A. No. 06-71 (GMS)
THIS DOCUMENT RELATES TO: ALL ACTIONS	)	

OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT OR, IF THAT MOTION IS DENIED, TO STAY THIS ACTION

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NATURE AND STAGE OF PROCEEDINGS

Plaintiffs filed separate purported class actions, which this Court consolidated by Order on April 5, 2006. (D.I. 13.)[1] Plaintiffs filed a Consolidated Class Action Complaint ("Complaint") on June 5, 2006, asserting claims against AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Aktiebolaget Hassle (collectively, "AstraZeneca") for (1) declaratory and injunctive relief under section 16 of the Clayton Act for alleged violations of Section 2 of the Sherman Act; (2) monopolization under state law; (3) unfair and deceptive trade practices under state law; and (4) unjust enrichment. (D.I. 17.) AstraZeneca has moved to dismiss the Complaint or, if that motion is denied, to stay the action pending the resolution of a related patent litigation. This is AstraZeneca's opening brief in support of that motion.

SUMMARY OF ARGUMENT

AstraZeneca developed, and now markets and sells, Toprol-XL® (*metoprolol succinate*), a popular drug for the treatment of hypertension, angina, and heart failure. Plaintiffs – a purported class of end-payors (consisting of alleged consumers and third-party payors) of Toprol-XL® – allege that, but for AstraZeneca's conduct in obtaining and seeking to enforce patents it held on Toprol-XL®, plaintiffs would have been able to purchase generic metoprolol succinate at a lower price than that paid for AstraZeneca's branded Toprol-XL®. Thus, plaintiffs allege, they have suffered damages.

Plaintiffs' allegations, however, do not state a valid claim because, for reasons unrelated to any conduct by AstraZeneca, plaintiffs have never been able to purchase

[1] Additional actions filed after the date of the Order were consolidated by the Court pursuant to the Order.

generic metoprolol succinate. That is because the Food and Drug Administration ("FDA") has not approved the application of any company to manufacture and sell a generic product. Plaintiffs attempt to avoid the consequences of that fact by alleging that AstraZeneca's filing of patent litigation against three generic manufacturers forced the FDA not to approve their applications. Under relevant law, the filing of patent litigation by a patent holder automatically stays ***final*** FDA approval of the proposed generic version for 30 months or until there is a judgment on patent validity or infringement. During those 30 months, however, the FDA is unrestricted in its ability to grant ***tentative*** approval to a generic drug application, irrespective of the ongoing patent litigation, and thereafter grant final approval when the stay ends or there is a judgment entered in the patent litigation (as there has been in this case).[2]

Here, plaintiffs fail to allege that the FDA granted tentative approval to the pending applications of three generic manufacturers while the patent litigation was before the district court, or that the FDA has granted final approval to any generic manufacturer after the 30-month stay expired or after judgment was entered in the patent litigation. Because the lack of even tentative FDA approval bars the generic manufacturers from

[2] The FDA has defined tentative approval:

> If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.

FDA, Center for Drug Evaluation & Research, *Drugs@FDA – Glossary of Terms*, http://www.fda.gov/cder/drugsatfda/glossary.htm.

competing in the relevant market, plaintiffs cannot demonstrate antitrust injury resulting from AstraZeneca's alleged actions, and their federal antitrust claim should be dismissed for lack of standing.

Once plaintiffs' only federal claim is dismissed, this Court should decline to exercise supplemental jurisdiction over the plaintiffs' state law claims. The Third Circuit has held that, if all federal claims are subject to dismissal, a district court should not exercise jurisdiction over remaining state law claims absent "extraordinary circumstances." *Tully v. Mott Supermarkets, Inc.*, 540 F.2d 187, 195 (3d Cir. 1976). No such circumstances exist here.

If the Court denies the motion to dismiss, the Court should stay this action. The Complaint alleges that AstraZeneca fraudulently secured patents related to Toprol-XL® and has unlawfully attempted to enforce those patents by filing sham lawsuits against three potential competitors. However, AstraZeneca is still litigating with those three generic manufacturers over the validity and enforceability of those very patents, and it makes little sense and would be wasteful to litigate this antitrust action before the patent litigation has concluded.

There can be no doubt that this litigation will be costly and burdensome, as the case involves, among other issues: complex issues related to patent validity; whether the patent litigation was objectively baseless; AstraZeneca's subjective intent in bringing the patent litigation; class certification issues; and difficult issues related to the relevant market definition, causation, and the measure of any damages. This effort by the parties and the Court may very well be wasted because the outcome of the patent litigation,

which is currently before the United States Court of Appeals for the Federal Circuit, could require dismissal of this action or at least narrow the issues in this case. The parties and the Court should not proceed with this immensely costly and burdensome litigation while the underlying patent litigation on which plaintiffs' claims are based is in progress, and a stay of this action until a final resolution of the patent litigation would thus best serve the interests of justice, judicial economy, and the parties.

STATEMENT OF FACTS

A. Overview

AstraZeneca markets metoprolol succinate under the brand name Toprol-XL®, which is an extended-release drug approved by the FDA for treating hypertension, angina, and congestive heart failure. (Compl., D.I. 17, ¶¶ 2, 64.) Plaintiffs have brought this putative class action lawsuit, alleging that they purchased and/or paid for Toprol-XL® during the period from May 5, 2005 to the present. (*Id.* ¶ 144.)

AstraZeneca owns United States patents relating to Toprol-XL®, including: U.S. Patent No. 5,001,161 (the "'161 patent") and U.S. Patent No. 5,081,154 (the "'154 patent"). (Compl. ¶¶ 4, 66-67.) The '161 patent issued on March 19, 1991, claiming "[a] sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier." (*Id.* ¶¶ 66, 72.) The '154 patent issued on January 14, 1992, claiming the composition of metoprolol succinate itself. (*Id.* ¶ 67.)

Plaintiffs do not allege that any generic manufacturer attempted to market a product to compete with Toprol-XL® before approximately 2003. (*Id.* ¶ 133.)

B. The FDA Approval Process

A company may not begin selling a new drug without FDA approval. 21 U.S.C. § 355(a). (Compl. ¶ 41.) Approval for a new drug must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b)(1). (Compl. ¶ 41.) NDA applicants must submit to the FDA a list of all patents that claim the drug for which FDA approval is being sought, or that claim a method of using that drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of

the drug. 21 U.S.C. § 355(b)(1), (c)(2). (Compl. ¶ 41.) Once the FDA approves the NDA, the FDA lists any patents referenced in the FDA Approved Drugs Products With Therapeutic Equivalence Evaluations, more commonly known as the "Orange Book." (*Id.*)

Generic drugs are drugs that the FDA has found to be bioequivalent to brand-name drugs. (*Id.* ¶ 49.) Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)), a generic manufacturer may file an Abbreviated New Drug Application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted to the FDA by the manufacturer of the brand-name drug. (Compl. ¶¶ 47, 55.)

As part of its ANDA, the generic manufacturer must make one of four certifications to the FDA:

I. that no patent for the pioneer drug has been filed with the FDA;

II. that the patent (or patents) for the pioneer drug has (or have) expired;

III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the generic manufacturer's proposed product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). (Compl. ¶ 57.)

The Hatch-Waxman Act provides an economic incentive to the first generic manufacturer that files a Paragraph IV Certification with its ANDA. That manufacturer

is granted a 180-day statutory period of market exclusivity during which time no other generic version of the drug can compete. (*Id.* ¶ 55.)

Any generic manufacturer that makes a Paragraph IV Certification must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). (Compl. ¶ 57.) The patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has a 45-day period in which to initiate a patent infringement suit against the applicant. 21 U.S.C. § 355(j)(5)(B)(iii). (Compl. ¶ 58.) If no action is initiated within 45 days, the FDA may approve the generic product, assuming all FDA requirements have been met. (*Id.*). If a patent infringement suit is brought within the 45-day window, final FDA approval is postponed until the earliest of (i) the expiration of the patent; (ii) 30 months from the patent holder's receipt of the Paragraph IV Certification (the "30-month stay"); or (iii) entry of a district court judgment of patent invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107.

Critically, the FDA is unrestricted in its ability to give tentative approval to the ANDA during the automatic 30-month stay. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.105(a). The litigation only delays *the effective date* of FDA approval. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. §§ 314.105(d), 314.107. *See generally Mylan Labs, Inc. v. Thompson*, 332 F. Supp. 2d 106, 111-12 (D.D.C. 2004) (discussing relationship between tentative and final FDA approval). A lack of tentative approval means that no generic version of the drug could have been marketed even in the absence of the patent litigation.

C. The Patent Litigation

In 2003 and 2004, AstraZeneca filed patent infringement lawsuits against KV Pharmaceutical Co. ("KV"); Andrx Pharmaceuticals, LLC and Andrx Corp. (collectively, "Andrx"); and Eon Labs, Inc. ("Eon") after those companies submitted to the FDA ANDAs for generic metoprolol succinate that contained a Paragraph IV Certification that the '161 and '154 patents were invalid and/or unenforceable. (Compl. ¶¶ 130-133.) Those lawsuits, which triggered the statutory 30-month stay, were ultimately consolidated in the United States District Court for the Eastern District of Missouri and styled as *In re Metoprolol Succinate Patent Litigation*, MDL Docket No. 1620 (E.D. Mo.). (Compl. ¶¶ 133-134 & n.5.) On January 17, 2006, the court in that action granted summary judgment to the generic manufacturers, finding that the AstraZeneca patents were invalid on the basis of double patenting and unenforceable based on a finding of inequitable conduct before the Patent and Trademark Office ("PTO"). (Compl. ¶ 140.) AstraZeneca has appealed the district court decision to the Federal Circuit.[3]

Plaintiffs do not allege that any of the generic manufacturers received tentative FDA approval of their ANDAs prior to the district court's decision, although the FDA could have granted such approval. On February 10, 2006, the district court entered judgment, which lifted the 30-month stay of final FDA approval. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)(a). Since that time, the FDA has not approved any of the pending ANDAs, and plaintiffs do not allege otherwise.

[3] AstraZeneca's appeal relates only to the '154 patent. AstraZeneca has requested the FDA delist the '161 patent from the Orange Book.

Plaintiffs could not state a claim even if the FDA had approved (or approves in the future) an ANDA after entry of judgment in the patent litigation. To state a claim, plaintiffs would have to show that an ANDA had received tentative approval while the 30-month stay was in effect. The stay – and the litigation that triggered the stay – could only be the cause of plaintiffs' alleged injury if the FDA would have approved the ANDA in the absence of the stay. Because the FDA can tentatively approve an ANDA irrespective of the stay, securing tentative approval would mean that the generic manufacturer could have marketed its generic drug but for the stay. Conversely, the failure to obtain tentative FDA approval while the stay is in place means that the generic company could not sell its product had there been no stay.

D. Plaintiffs' Allegations

Following the district court decision in the patent litigation, plaintiffs brought this lawsuit. The crux of plaintiffs' allegations is that AstraZeneca "prevented generic versions of Toprol-XL from entering the market." (Compl. ¶ 3.) AstraZeneca pursued this objective, according to plaintiffs, through misconduct before the PTO (*id.* ¶ 4), an improper listing of patents in the Orange Book (*id.*), and the supposedly "sham" lawsuits filed against the three ANDA filers, which were filed "to frustrate or delay market availability of generic bioequivalents." (*Id.* ¶¶ 4, 10.) Although no generic drug manufacturer filed an ANDA until 2003, and although there are no allegations that any of the three generic manufacturers who have filed ANDAs have received even tentative approval from the FDA, plaintiffs further allege that the patent lawsuits "were nevertheless able to block generic competition for an extended period of time." (*Id.*

¶ 11). Plaintiffs allege that, if generic metoprolol succinate were available, they would have paid less than they otherwise would have for extended-release metoprolol succinate. (*Id.* ¶¶ 18-32.)

ARGUMENT

I. STANDARD OF REVIEW

Plaintiffs' complaint should be dismissed pursuant to Rule 12(b)(6) "if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff[s'] favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc.*, 140 F.3d 478, 483 (3d Cir. 1998). A court will "draw on the allegations of the complaint, but in a realistic, rather than a slavish, manner." *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 (3d Cir. 1998). For example, a court need not accept as true "unsupported conclusions and unwarranted inferences." *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997). Nor can the court "assume that the [plaintiff] can prove facts that it has not alleged." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

In a case where plaintiffs' antitrust standing is at issue, the "courts have an obligation in matters before them to view the complaint as a whole and to base rulings not upon the presence of mere words but, rather, upon the presence of a factual situation which is or is not justiciable." *West Penn Power*, 147 F.3d at 263.

II. PLAINTIFFS' FEDERAL ANTITRUST CLAIM SHOULD BE DISMISSED BECAUSE PLAINTIFFS CANNOT ESTABLISH ANTITRUST STANDING

Plaintiffs allege that they have been injured as a result of alleged violations of Section 2 of the Sherman Act. (Compl. ¶¶ 151-158.) This claim should be dismissed for lack of "antitrust standing" because plaintiffs cannot establish that they have suffered an injury "by reason of" the alleged antitrust violations as required by *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977). Plaintiffs allege that, as a result of AstraZeneca's conduct, no generic competition in the metoprolol succinate market exists, and as a result, they are forced to pay higher prices for AstraZeneca's branded version. The potential generic competitors, however, are legally prohibited by federal law and FDA regulations from selling their generic versions of metoprolol succinate. Because these FDA regulations constitute an independent bar against the generic manufacturers competing in the market for metoprolol succinate, plaintiffs' alleged injuries cannot be "by reason of" AstraZeneca's alleged conduct. *See West Penn Power*, 147 F.3d at 264-65; *Schuylkill Energy Res.*, 113 F.3d at 413. Thus, plaintiffs' antitrust claim should be dismissed as a matter of law.

A. Plaintiffs' Antitrust Claim Must Be Dismissed If Plaintiffs Cannot Establish "Antitrust Injury"

An antitrust plaintiff is barred as a matter of law from asserting its claims if it cannot establish antitrust standing. *Associated Gen. Contractors of Cal.*, 459 U.S. at 529-33; *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 181 (3d Cir. 1997). The requirement of antitrust standing applies equally to claims for damages and for injunctive relief. *Cargill, Inc. v. Monfort, Inc.*, 479 U.S. 104, 109-10 (1986); *West*

Penn Power Co., 147 F.3d at 263. A threshold requirement for establishing antitrust standing is proof of the existence of "antitrust injury." *Brunswick*, 429 U.S. at 489. To show antitrust injury, an antitrust plaintiff must establish that it suffered an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Id.* If an antitrust plaintiff cannot prove antitrust injury, the claims must be dismissed. *See id.*; *West Penn Power*, 147 F.3d at 263.

Proof of antitrust injury requires two showings. First, a plaintiff must establish that "but for" the alleged antitrust violation the plaintiff would not have suffered the same injury. *West Penn Power*, 147 F.3d at 265 (stating that antitrust injury depends on "causal connection between the purportedly unlawful conduct and the injury"). Second, a plaintiff must show that its injury is of the type the antitrust laws were designed to prevent and that it flows from the defendant's anticompetitive conduct. *Brunswick*, 429 U.S. at 488-89; *West Penn Power*, 147 F.3d at 265; *Schuylkill Energy Res.*, 113 F.3d at 413.

B. Plaintiffs Cannot Establish Antitrust Injury from AstraZeneca's Alleged Conduct Because Federal Law and FDA Regulations Are an Absolute Bar to Generic Competition in the Relevant Market

Plaintiffs cannot show that they suffered antitrust injury in the alleged relevant market. In their complaint, plaintiffs allege the relevant market to be "the market for the manufacturer and sale of Toprol-XL, metoprolol succinate, and all generic bioequivalents rated 'AB' by the FDA." (Compl. ¶ 39.) Plaintiffs' allegations make clear that their only alleged injury flows from the inability of generic manufacturers to compete in the market for metoprolol succinate. (*Id.* ¶¶ 154-155.)

Plaintiffs' antitrust claim should be dismissed because they cannot satisfy either of the required showings for antitrust injury. First, AstraZeneca's alleged conduct cannot be the "but for" cause of plaintiffs' alleged injury because federal law and FDA regulations have prohibited and continue to prohibit the three generic manufacturers from selling generic versions of metoprolol succinate. The independent and absolute FDA prohibition against KV, Andrx, and Eon entering the metoprolol succinate market "cuts the causal chain" between AstraZeneca's alleged antitrust violations and plaintiffs' alleged injuries. *See West Penn Power*, 147 F.3d at 268. Second, plaintiffs cannot show injury from anticompetitive behavior in the relevant market – by definition – because KV, Andrx, and Eon are legally prohibited from competing in that market. *See Schuylkill Energy Res.*, 113 F.3d at 415.

Courts have dismissed antitrust claims in cases involving disputes between brand-name and generic drug manufacturers where no generic manufacturer received tentative approval before the 30-month stay expired. For instance, in *Bristol-Myers Squibb Co. v. Copley Pharmaceutical, Inc.*, 144 F. Supp. 2d 21 (D. Mass. 2000), Copley filed an ANDA for approval of a generic version of the drug at issue. *Id.* at 22. Bristol-Myers sued Copley for patent infringement, and Copley brought antitrust counterclaims. *Id.* The court dismissed the antitrust counterclaims, because "Copley lacks standing because the statutory scheme, not its lawsuit, prevents Copley from entering the market." *Id.* at 23. Just as plaintiffs here allege that the patent litigation has delayed FDA approval, Copley argued that "it cannot receive approval because Bristol's lawsuit suspends the FDA approval process until the litigation ends or until Bristol's patent is declared

invalid." *Id.* The court answered succinctly: "Copley is incorrect." *Id.* Relying on the fact that Copley could have received tentative FDA approval during the patent litigation, and citing the Third Circuit opinion in *West Penn Power*, the court reasoned: "Without tentative FDA approval, Copley could not now enter the market, regardless of the pending litigation." *Id.*; *see also id.* at 24-25 ("Like the defendant in [*West Penn Power*], Copley has not received the tentative regulatory approval required for market entry."). Likewise, here, plaintiffs in this action have failed to allege that KV, Andrx, or Eon has received tentative approval.

In *In re Terazosin Hydrochloride Antitrust Litigation*, 335 F. Supp. 2d 1336 (S.D. Fla. 2004), Abbott Laboratories ("Abbott") held patents covering a brand-name drug and filed seventeen patent infringement lawsuits against generic companies that had submitted ANDAs seeking to market generic versions of the drug at issue. *Id.* at 1341. Subsequently, direct and indirect purchasers and several States sued Abbott, alleging, among other things, claims under Section 2 of the Sherman Act. *Id.* at 1342-43. The court granted Abbott's motion for summary judgment on several grounds, one being that the ANDA filers had not received tentative FDA approval before the patent litigations had concluded. *Id.* at 1367-69. As in *Copley*, the *Terazosin* court recognized that tentative FDA approval is not stayed pending the patent litigation. *Id.* at 1368 n.31 ("[I]t is undisputed that the FDA may grant tentative approval even though a pioneer drug company has filed a Hatch-Waxman infringement suit and tentative approval is the essential step before a generic drug maker can enter the drug market."). The court held that plaintiffs lacked antitrust standing because "[i]f the ANDA applicant has not even

received *tentative* FDA approval, there can be no causal connection between these lawsuits and the alleged antitrust injury." *Id.* For the same reasons, plaintiffs here have failed to allege antitrust standing.[4]

The need to establish tentative FDA approval was also demonstrated in *In re Relafen Antitrust Litigation*, 286 F. Supp. 2d 56 (D. Mass. 2003). SmithKline Beecham ("SmithKline") held a patent covering the brand-name drug, and three generic companies filed ANDAs seeking to market generic versions. *Id.* at 60. SmithKline filed suit for patent infringement against the three on October 27, 1997, November 13, 1997, and February 17, 1998, respectively. *Id.* During the patent litigation, which the generic companies eventually won, the FDA issued tentative approval to two of the generic companies – on August 8, 1998 and December 24, 1998 – with final approval stayed until May 2000, which was the end of 30-month automatic stay. *Id.* Plaintiffs in the subsequent antitrust suit, purchasers of the brand-name drug, did not file their suit until more than four years after SmithKline initially filed the patent infringement litigation. *Id.* SmithKline moved to dismiss the complaint on the ground that the antitrust action was filed outside of the four-year limitations period from the act complained of – the filing of the alleged sham patent lawsuit. *Id.* at 61-62. The court denied the motion on the ground that the basic accrual or speculative damages exception to the statute of limitations applied. The court held that – prior to the first generic company receiving tentative FDA approval on August 8, 1998 – no antitrust claim had even accrued. *Id.* at 63-64 ("[N]o

[4] Although the *Terazosin* court was deciding a motion for summary judgment, the court's ruling is applicable to this motion to dismiss. Plaintiffs have failed to allege that KV, Andrx, or Eon has received tentative FDA approval, and no amount of discovery can change that because these companies have not received tentative approval.

cause of action would lie for the plaintiff purchasers against Smithkline when Smithkline filed suit because the plaintiffs would have been unable to plead any damages, other than those of a purely speculative variety."). The *Relafen* court's holding that there is no cognizable antitrust claim until a generic manufacturer secures tentative FDA approval confirms that there likewise is no antitrust standing in this case.

These cases are consistent with Third Circuit precedent. In *West Penn Power*, the City of Pittsburgh brought suit seeking damages and injunctive relief against two power companies that had entered an agreement not to seek regulatory approval to compete in certain City Redevelopment Zones. 147 F.3d at 258. The Third Circuit held that the City could not show antitrust injury because state utilities regulations legally barred one of the utilities from competing in those areas at that time without regulatory approval. *Id.* at 263. Even though one of the utilities had applied for regulatory approval, the current lack of regulatory approval was an intervening cause, the court reasoned, which "cuts the causal chain" between the alleged injury and the alleged antitrust violation. *Id.*; *see also id.* at 267 ("Since the realization of competition is in the hands of regulators there is *no way* that the City can show that competition would have occurred absent the concerted activity between the two utilities." (emphasis supplied)). Accordingly, the Third Circuit affirmed the dismissal of the City's claims.

In *Schuylkill Energy Resources, Inc.*, an independent power producer, SER, brought a Sherman Act monopolization claim against a utility, PP&L. 113 F.3d at 411-13. SER alleged that PP&L improperly curtailed energy purchased from SER in order to monopolize the relevant energy market. *Id.* at 412-13. The Third Circuit held that SER

could not establish antitrust injury for its monopolization claim because SER was legally prohibited from competing in the relevant market. *Id.* at 415. As the court explained:

> The antitrust laws are intended to preserve competition for the benefit of consumers in the market in which competition occurs . . . . The requirement that the alleged injury be related to anti-competitive behavior requires, as a corollary, that the injured party be a participant in the same market as the alleged malefactors. . . . A plaintiff who is neither a competitor nor a consumer in the relevant market does not suffer antitrust injury.

Id. (alterations in original) (quoting *Vinci v. Waste Mgmt., Inc.*, 80 F.3d 1372, 1376 (9th Cir. 1996)). Because SER could not legally compete in the relevant market, its antitrust claims for damages and injunctive relief were properly dismissed. *Id.*

Plaintiffs' federal antitrust claim should likewise be dismissed. As in *West Penn Power* and *Schuylkill Energy Resources*, KV, Andrx, and Eon are legally prohibited from competing in the alleged relevant market. Federal law and FDA regulations barring the introduction of generic competition until FDA approval is secured – like the governmental regulations in *West Penn Power* and *Schuylkill Energy Resources* – are an independent bar to competition in the alleged relevant market and prevent plaintiffs from proving either causation in fact or an injury from anticompetitive behavior. *See* 2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 338b, at 320 (2d ed. 2000) ("[A] plaintiff cannot be injured in fact by private conduct excluding it from the market when a statute prevents the plaintiff from entering that market in any event.").

Plaintiffs' allegation that AstraZeneca delayed generic competition for 30 months simply by filing patent infringement lawsuits against KV, Andrx, and Eon does not change the result. (Compl. ¶¶ 11, 134.) Although *final* FDA approval of an ANDA is

stayed under the Hatch-Waxman Act when a pioneer drug maker institutes patent litigation, there can be no dispute that an ANDA may receive *tentative* FDA approval irrespective of the existence of the patent litigation, thus putting the generic manufacturer in a position to compete immediately in the market once the 30-month stay is lifted or expires. *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 203-04 (E.D.N.Y. 2003) (describing process by which generic manufacturer received tentative FDA approval during a Hatch-Waxman patent infringement litigation and holding that these allegations "adequately show" that the generic company would have likely received final FDA approval when the 30-month stay expired). Accordingly, if an ANDA filer does not secure tentative FDA approval – and none has here – it is the generic manufacturer's failure to satisfy FDA regulations that explains the absence of generic metoprolol succinate from the market, regardless of any pending litigation.[5]

Plaintiffs' allegation that the 30-month stay is the cause of the lack of generic competition is also undercut by events since entry of the judgment in the patent litigation. None of the pending ANDA applications has been approved since judgment was entered on February 10, 2006. If the automatic stay provision (and not FDA approval) were responsible for keeping generic metoprolol succinate from the market, then the lifting of that stay upon the entry of the district court's ruling in the patent litigation in February 2006 should have immediately ushered in generic competition. The incontrovertible fact

[5] There are numerous reasons why a generic drug manufacturer may fail to secure tentative FDA approval. Under 21 U.S.C. § 355(j)(4), the FDA must approve an ANDA unless the FDA determines that at least one of a list of disqualifying criteria is present. In any event, for whatever reasons, KV, Andrx, and Eon are not alleged to have obtained tentative FDA approval.

is that it is the generic manufacturers' inability to receive any FDA approval that has kept generic metoprolol succinate from the market.

In a nutshell, plaintiffs lack standing as a matter of law because, without tentative FDA approval, no generic version of metoprolol succinate could have been marketed even in the absence of AstraZeneca's alleged conduct. Therefore, plaintiffs' federal antitrust claim should be dismissed.

C. Plaintiffs' Do Not and Cannot Allege That AstraZeneca's Conduct Hindered Tentative Approval of the Pending ANDAs

It is impossible for plaintiffs to allege that any of the three generic manufacturers received tentative FDA approval while the 30-month stay was in place – because none did. *See West Penn Power*, 147 F.3d at 266 (holding that because the court could "determine from the face of the complaint" that the potential competitor did not have regulatory approval to enter the market, the claimed antitrust violation was not actionable). In addition, the Complaint does not allege that the FDA would have actually approved any of the ANDAs, let alone any facts that would permit this Court to conclude that FDA approval was likely. *See West Penn Power*, 147 F.3d at 268 ("There are no facts averred in the complaint which even permit us to speculate as to the likelihood of the [regulator] granting certification to [the applicant].").

Moreover, plaintiffs do not, and cannot, allege that AstraZeneca hindered tentative FDA approval of the ANDAs. As described earlier, such allegations would be futile because the FDA is unrestricted in its ability to grant tentative approval to a generic drug application, irrespective of the ongoing patent litigation. And no amended complaint could set forth facts showing that AstraZeneca's conduct affected the tentative

approval process because ANDA filers are incentivized to pursue tentative approval of their ANDAs even if the patent holder has filed litigation.

Like any rational company, a generic manufacturer that is the first ANDA filer (as the three generic companies are in this case for the respective doses for which they seek to compete) would prefer to obtain approval expeditiously so that it will be in a position to maximize sales of its product and not potentially lose any portion of the 180-day period of generic exclusivity that Hatch-Waxman provides. A generic manufacturer that has won tentative FDA approval during the patent litigation could come to market much sooner than if it waited until the patent litigation concluded to focus on its ANDA. It is unsurprising, therefore, that there are numerous examples of generic companies, including some of the same ANDA filers here, pursuing and receiving tentative FDA approval despite having been sued for patent infringement. *See, e.g.*, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902 (6th Cir. 2003) ("On September 15, 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved as soon as it was eligible, either upon expiration of the thirty-month waiting period in early July 1998, or earlier if the court in the patent infringement action ruled that the '584 patent was not infringed."); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1372 & n.2 (Fed. Cir. 2002) ("In September 2000 Andrx had received tentative approval of its ANDA from the FDA" pending the February 25, 2001 expiration of the stay.); *Elan Corp., PLC v. Andrx Pharms., Inc.*, 272 F. Supp. 2d 1325, 1330 (S.D. Fla. 2003) ("The FDA granted the Andrx ANDA tentative approval on March 17, 2000" while patent litigation continued.); *Relafen*, 286 F. Supp. 2d at 60 ("On August 8, . . . the FDA issued

tentative approval to Eon's . . . generic nabumetone product[], but the FDA withheld final approval until the conclusion of the thirty-month stay period.").

In addition, ANDA filers are incentivized to pursue tentative FDA approval because under *Copley*, *Terazosin*, *Relafen* and related authority, such as *West Penn Power*, generic manufacturers must obtain tentative FDA approval during the patent litigation as a prerequisite for bringing antitrust counterclaims against the brand-name manufacturer – a common feature of Hatch-Waxman patent litigations. Moreover, a generic manufacturer that obtains tentative FDA approval may well increase the settlement value of the patent litigation because it increases substantially the likelihood that a competitor would enter the market at the conclusion of the litigation. There is no rational basis to the allegation that the ANDA filers did not and could not focus on an ANDA because of the patent litigation.

In sum, plaintiffs have failed sufficiently to allege that they have antitrust standing because the harm they allege – the lack of competition in the metoprolol succinate market – is the result of the generic manufacturers' failure to secure FDA approval of their ANDAs, and not the result of AstraZeneca's alleged conduct.

D. Other Courts Have Misperceived the Importance of Tentative FDA Approval

AstraZeneca recognizes that other courts have held that the FDA's failure to approve an ANDA is not an absolute bar to an antitrust claim. Certain of these decisions conclude that the 30-month stay prevents the FDA from approving an ANDA, but they have no bearing on AstraZeneca's argument here because they do not even address the fact that the FDA may grant tentative approval while the stay is in effect. *See, e.g.*,

Warner Lambert Co. v. Purepac Pharm. Co., Civil Action No. 98-02749(JCL), 2000 U.S. Dist. LEXIS 22559 (D.N.J. Dec. 22, 2000).

Other such cases do mention tentative FDA approval, but these cases misperceive the importance of such approval. *See, e.g.*, *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751 (E.D. Pa. 2003); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540 (D.N.J. 2000). In *Ben Venue*, the court accepted, and appears to have been significantly influenced by the generic company's representation at oral argument that "generic manufacturers have had little practical incentive to pursue even conditional [FDA] approval." 90 F. Supp. 2d at 545. This premise is incorrect. As explained earlier, *see* supra pp. 19-20, a generic manufacturer has the incentive to pursue tentative FDA approval during the litigation.

Moreover, *Ben Venue* was decided before *Copley*, *Terazosin*, and *Relafen*, so the court did not have the opportunity to review these newer cases that focus on the importance of tentative FDA approval in the antitrust standing inquiry. *See, e.g.*, *Terazosin*, 335 F. Supp. 2d at 1368 n.31 ("[I]t is undisputed that the FDA may grant tentative approval even though a pioneer drug company has filed a Hatch-Waxman infringement suit and tentative approval is the essential step before a generic drug maker can enter the drug market."). Moreover, to the extent *Ben Venue* conflicts with *West Penn Power* – which held that "[t]he presence of the regulatory scheme and need for approval . . . cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise," 147 F.3d at 267-68 – *West Penn Power* controls.

In *Wellbutrin*, the court did not focus on the issue of tentative approval or the incentives of generic manufacturers to obtain such approval during the 30-month stay. And like the court in *Ben Venue*, the *Wellbutrin* court did not address the decisions in *Copley*, *Terazosin* and *Relafen* and failed adequately to apply *West Penn Power*.

For these reasons, this Court should rely on those cases that have appropriately considered the importance of tentative FDA approval and, under that authority, dismiss plaintiffs' federal antitrust claim.

III. THE COURT SHOULD DECLINE TO EXERCISE SUPPLEMENTAL JURISDICTION OVER THE PLAINTIFFS' STATE LAW CLAIMS

Plaintiffs' state law claims alleging monopolization, unfair and deceptive trade practices, and unjust enrichment should be dismissed as an exercise of this Court's discretion to decline supplemental jurisdiction. Under 28 U.S.C. § 1367(c), "[t]he district courts may decline to exercise supplemental jurisdiction over a [state law claim] if . . . the district court has dismissed all claims over which it had original jurisdiction." Upon dismissal of the plaintiffs' federal antitrust claim, there are no remaining federal claims.

Although supplemental jurisdiction is a doctrine of discretion, the Supreme Court has stated that its exercise should be declined when federal claims are dismissed at an early stage of the litigation:

> Needless decisions of state law should be avoided both as a matter of comity and to promote justice between the parties, by procuring for them a surer-footed reading of applicable law. Certainly if the federal claims are dismissed before trial, even though not insubstantial in a jurisdictional sense, the state claims should be dismissed as well.

United Mine Workers v. Gibbs, 383 U.S. 715, 726 (1966).

The Third Circuit has confirmed that, if all federal claims are subject to dismissal, a district court should not exercise jurisdiction over remaining state law claims absent "extraordinary circumstances." *Tully v. Mott Supermarkets, Inc.*, 540 F.2d 187, 195 (3d Cir. 1976); *see also City of Pittsburgh Comm'n on Human Relations v. Key Bank USA, NA*, 163 F. App'x 163, 165-66 (3d Cir. 2006); *Schaffer v. Bd. of Sch. Directors*, 730 F.2d 910, 912 (3d Cir. 1984). In *Tully*, the court held that "substantial time devoted to the case" and "expense incurred by the parties" do not constitute extraordinary circumstances. *Id.* at 196. Plaintiffs cannot demonstrate that any extraordinary circumstances exist here, and thus the Court should decline to exercise supplemental jurisdiction over the state law claims.

IV. IF THE MOTION TO DISMISS IS DENIED, THE COURT SHOULD STAY THIS ACTION UNTIL FINAL RESOLUTION OF THE PENDING PATENT LITIGATION

If the Court does not dismiss plaintiffs' action, it should stay all proceedings in this action pending resolution of the related patent litigation between AstraZeneca and the generic manufacturers because a stay would best serve the interests of justice, judicial economy, and the parties. Courts have long decried costly, burdensome, and unnecessary litigation. *See, e.g.*, *Del. River Port Auth. v. FOP, Penn-Jersey Lodge 30*, 290 F.3d 567, 572 n.12 (3d Cir. 2002); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997). There can be no doubt that this litigation will be costly and burdensome, as the case involves, among other issues: complex issues relating to patent validity; whether the patent litigation was objectively baseless; AstraZeneca's subjective intent in bringing the patent litigation; class certification issues; and difficult issues related to the

relevant market definition, causation, and the measure of any damages. This effort by the parties and the Court may very well be wasted because the outcome of the patent litigation between AstraZeneca and three generic manufacturers over the validity and enforceability of the patents related to Toprol-XL® could require dismissal of this action or at least narrow the issues in this case.

It is axiomatic that "the power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel and for litigants." *Landis v. North American Co.*, 299 U.S. 248, 254 (1936). The interests of judicial economy and fairness are of the greatest importance to a court when determining whether to stay an action. *Id.* at 254. It is well established that "[i]n the exercise of its sound discretion, a court may hold one lawsuit in abeyance to abide the outcome of another which may substantially affect it or be dispositive of the issues." *Bechtel Corp. v. Local 215, Laborers' Int'l Union*, 544 F.2d 1207, 1215 (3d Cir. 1976).[6] It is not necessary that either the parties to the cases or the issues in the cases be identical if the outcome of the first matter could impact the other. *See, e.g.*, *Landis*, 299 U.S. at 254.

Courts are guided by several factors in exercising their discretion to stay an action, including: "' (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to a the non-moving party; (2) whether a stay will simplify the issues in

[6] *See also, e.g.*, *Commissariat A. L'Energie Atomique v. Dell Computer Corp.*, No. Civ.A. 03-484-KAJ, 2004 U.S. Dist. LEXIS 9107 (D. Del. May 13, 2004) (granting motion to stay because the resolution of issues raised in parallel patent infringement against another group of defendants would simplify the issues in the stayed case); *Chartener v. Provident Mut. Life Ins. Co.*, No. Civ.A 02-8045, 2003 U.S. Dist. LEXIS 19500, at *8 (E.D. Pa. Oct. 21, 2003) (granting motion to stay where "[i]t is clear that the final outcome of state court proceedings will have a substantial effect on, if not dispose of, some or all of Plaintiff's claims before this court").

question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set.'" *In re Pharmastem Therapeutics, Inc. Patent Litig.*, No. 05-md-1660 GMS (D. Del. Oct. 6, 2005) (order granting stay motion) (quoting *Xerox Corp. v. 3 Comm Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999)). (Ex. A.) Each of these three factors weighs heavily in favor of granting a stay of all proceedings in this action.

A. Plaintiffs Will Not Be Unduly Prejudiced By a Stay or Be Presented with a Clear Tactical Disadvantage

Although all plaintiffs have an interest in the prosecuting their claims, plaintiffs here will not be *unduly* prejudiced by a stay of this action. AstraZeneca is seeking a stay that would last only as long as necessary. The patent litigation is already on appeal to the Federal Circuit, and the outcome of that appeal and any subsequent proceedings could "substantially affect" or "be dispositive of" this case. *See Bechtel Corp.*, 544 F.2d at 1215. In that event, staying this action would conserve the resources of plaintiffs. *See In re Pharmastem Therapeutics*, slip. op., at 4. Moreover, there is no conceivable tactical disadvantage to plaintiffs. Once the patent litigation is finally concluded, this case will be dismissed (voluntarily or otherwise) or the issues will be clarified and the parties can resume the litigation from where it stands now.

B. A Stay Will Simplify the Issues in Question and Best Serve the Interests of Judicial Economy

Staying this action would best serve the interests of judicial economy for several reasons. First, if the Federal Circuit or the district court on remand determines that AstraZeneca's patents are valid and enforceable, then *all* of the issues in this litigation may well be moot. That is so because AstraZeneca's attempt to enforce its patent rights through litigation is presumptively immune from antitrust scrutiny under the *Noerr-*

Pennington doctrine. *See, e.g., Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965); *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 509-10 (1972); *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993). There is a narrow exception to *Noerr-Pennington* immunity, often referred to as the "sham" exception. *California Motor Transp.*, 404 U.S. at 511. To invoke this exception, a plaintiff must establish that (i) the litigation in question is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and (ii) subjectively, the litigation was in fact "an attempt to interfere *directly* with the business relationships of a competitor through the use of a governmental *process* – as opposed to the *outcome* of that process – as an anticompetitive weapon." *Prof'l Real Estate Investors*, 508 U.S. at 60-61 (internal citations and quotations marks omitted). Unless litigation is "objectively baseless," the second prong of the sham litigation exception is irrelevant. *Id.* at 60.

A winning lawsuit obviously cannot be "objectively baseless." *Id.* at 60 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). But even a result short of full vindication for AstraZeneca may require dismissal of the Complaint. For example, the patent litigation cannot be a "sham" if AstraZeneca prevails on some of its claims. *See, e.g., Eden Hannon & Co. v. Sumitomo Trust & Banking Co.*, 914 F.2d 556, 564-65 (4th Cir. 1990) (holding that suit was not sham litigation when plaintiff succeeded on one of its four claims); *Dentsply Int'l, Inc. v. New Tech. Co.*, No. 96-272, 1996 U.S. Dist. LEXIS 19846, at *9 (D. Del.

Dec. 19, 1996) (noting that "if plaintiffs prevail on one of their counts, the sham aspect of the antitrust [claim] must fail"). Also, if the Federal Circuit determines that AstraZeneca's claims of patent infringement should not have been resolved on summary judgment, that would imply that the lawsuit was not objectively baseless. *See, e.g.*, *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1080-81 & n.4 (8th Cir. 1999) (holding that denial of Rule 50(a) motion for judgment as a matter of law demonstrates that patent infringement action was not lacking in probable cause or otherwise objectively baseless); *Gen-Probe, Inc. v. Amoco Corp.*, 926 F. Supp. 948, 958-59 (S.D. Cal. 1996) (holding that fact that two of the lawsuits survived summary judgment meant that they could not be sham litigation); *Bio-Technology Gen. Corp. v. Genetech, Inc.*, 886 F. Supp. 377, 382 (S.D.N.Y. 1995) (finding that plaintiff failed to allege "sham" when defendant had survived six motions for summary determination), *aff'd*, 267 F.3d 1325, 1332-33 (Fed. Cir. 2001); *Harris Custom Builders, Inc. v. Hoffmeyer*, 834 F. Supp. 256, 261-62 (N.D. Ill. 1993) (holding that surviving summary judgment meant that patent infringement claim was not objectively baseless). These examples are not exhaustive, but illustrate that there are numerous outcomes in the patent litigation that would substantially affect this case or even require this Court to dismiss it.[7]

[7] If the Federal Circuit affirms the district court, and there are no further proceedings in the patent litigation, that of course does not mean that AstraZeneca's patent infringement lawsuits were objectively baseless. As the Supreme Court has stated:

> On the other hand, when the antitrust defendant has lost the underlying litigation, a court must resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation. The court must remember that even when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable ground for bringing suit.

Second, a stay would conserve judicial resources and prevent undue hardship to AstraZeneca. Without a stay, the Court will have to devote considerable resources to this complex antitrust action, despite the possibility that the effort will be mooted by developments in the patent litigation. Likewise, the parties will have to spend a very significant amount of money, time, and resources to this case. Allowing this action to proceed, requiring the Court to oversee discovery, and the briefing of the complex patent and legal issues involved in this case, would be an inefficient use of court resources if ultimately the outcome of the patent litigation narrows the issues or requires dismissal of plaintiffs' Complaint. *See In re Pharmastem Therapeutics*, slip op., at 4 ("For example, if the Federal Circuit determines that PharmaStem's patents are invalid, then many of the issues in the litigation would become moot. A stay, therefore, will conserve the resources of the parties and the court.").

Further, a stay which permits the patent litigation to run its course eliminates the risk that this Court could issue an opinion regarding the patents that conflicts with the decisions in the patent litigation. In the event that conflicting opinions are issued, even more resources will be spent resolving the inconsistencies that would result.

C. A Stay at This Stage of the Litigation Is in the Best Interests of the Parties and the Court

The fact that this litigation is still in the early stages also weighs in favor of granting a stay. Discovery has not yet begun and no scheduling conference has been held. *See In re Pharmastem Therapeutics*, slip op., at 4-5 ("Lastly, the parties have not commenced with discovery and no trial date has been set. Thus, the court concludes that

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Prof'l Real Estate Investors, 508 U.S. at 60 n.5 (internal citations and quotation marks omitted).

the balance of harms weighs in favor of granting a stay."). Because discovery would be extensive and the issues in this litigation hotly contested, it is in the best interests of justice and efficiency to stay this action before significant time and resources are spent on an action that could very well be mooted by the outcome of the patent litigation.

CONCLUSION

For the reasons set forth above, AstraZeneca respectfully requests that this Court enter an order dismissing plaintiffs' Complaint or, if the motion to dismiss is denied, an order staying all proceedings in this action, including any motions, pleadings, and discovery, pending the entry of a final decision in the patent litigation.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on June 27, 2006 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to Gary F. Traynor and A. Zachary Naylor.

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE:	)	
PHARMASTEM THERAPEUTICS, INC. PATENT LITIGATION	)	MDL Docket No. 05-md-1660 GMS JUDGE GREGORY M. SLEET

ORDER

1. This case arises from a February 17, 2005 Order from Judicial Panel on Multidistrict Litigation, which consolidated six actions pending in five district courts and transferred them to this court. Five of the actions are patent infringement actions brought by PharmaStem Therapeutics, Inc. ("PharmaStem") against medical providers and blood banks.[1] The sixth action is an antitrust and state law tort action brought by ViaCell, Inc. ("ViaCell"), CorCell, Inc. ("CorCell"), and Cryo-Cell International, Inc. ("Cryo-Cell").[2] These cases are related to patent infringement litigation that PharmaStem initiated in the District of Delaware in February 2002.

2. On February 22, 2002, PharmaStem filed a lawsuit against ViaCell, Cryo-Cell, CorCell, StemCyte, Inc. ("StemCyte"), CBR Systems, Inc. ("CBR"), Birthcells Technology, Inc.

[1] The five patent infringement actions are styled as follows: *PharmaStem Therapeutics, Inc. v. Cord Blood Registry, Inc., et al.*, C.A. No. C-04-3072-JSW (N.D. Cal.), *PharmaStem Therapeutics, Inc. v. CureSource, Inc., et al.*, C.A. No. SA-CV-04-921-GLT (C.D. Cal.), *PharmaStem Therapeutics, Inc. v. CorCell, Inc., et al.*, C.A. No 2:04-CV-03561-RK (E.D. Pa.), *PharmaStem Therapeutics, Inc. v. CryoCell Int'l, Inc., et al.*, C.A. No. 8:04-CV-1740-T-30TGW (M.D. Fla.), and *PharmaStem Therapeutics, Inc., v. ViaCell, Inc., et al.*, C. A. No. 04-CV-11673-RWZ (D. Mass.).

[2] The antitrust action, *ViaCell, Inc. v. PharmaStem Therapeutics, Inc.*, C.A. No. 04-1335-GMS (D. Del.), was filed in the District of Delaware on October 5, 2004.

("Birthcells"), Nustem Technologies, Inc. ("Nustem"), and Bio-Cell, Inc. ("Bio-Cell"), alleging infringement of United States Patent Nos. B1 5,004,681 ("'681 Patent") and 5,192,553 ("'553 Patent").

3. On October 29, 2003, the jury returned a unanimous verdict on all claims in favor of Pharmastem. The parties then filed several post-trial motions. On September 15, 2004, the court issued a Memorandum Opinion and Order (the "Post-trial Order"), concluding that the defendants do not infringe the '553 patent and granting a partial new trial on the issue of infringement and damages with respect to the '681 patent.

4. On September 29, 2004, the defendants filed a motion for partial reconsideration of the court's Post-trial Order. The motion requested the court to enter judgment as a matter of law in the defendants' favor, regarding their alleged infringement of the '681 patent. On December 14, 2004, the court issued an Order granting the defendants' request, based on PharmaStem's failure to present sufficient evidence upon which the jury could find infringement of the '681 patent.

5. On January 6, 2005, PharmaStem appealed the court's September 15, 2004 and December 14, 2004 decisions to the Federal Circuit. PharmaStem filed its initial appellate brief on September 15, 2005, and the defendants' initial response brief is due October 31, 2005.

6. On July 19, 2005, the court issued a Practice and Procedure Order (D.I. 21), setting an initial pretrial conference in the transferred Multidistrict Litigation ("MDL") for October 6, 2005. The Order also directed the parties to submit briefing, as well as a proposed case management plan and agenda, in preparation for the conference.

7. On September 29, 2005, the parties submitted a Joint Proposed Case Management Plan and Agenda for Initial Pretrial Conference (D.I. 25) (the "Agenda"). The Agenda states that the parties were not able to agree on a proposed schedule and sets forth the parties' respective proposals.

8. PharmaStem proposes that discovery should begin immediately after the initial conference, but that claim construction briefing, if necessary, and dispositive motions should be filed after the Federal Circuit renders its decision in Case No. 05-1490 and cross-appeals Case No. 05-1551 (the "pending appeals"). PharmaStem wishes to move forward with the MDL because it has only a few more years of patent exclusivity, and is "gravely concerned about the lack of enforcement of its valid patents against actual and potential infringers participating in the cord blood industry." (D.I. 24, at 8.) According to PharmaStem, "[a]llowing the defendants . . . to use their dominant positions in the private cord blood banking market to continue to grow their infringing businesses before this MDL is adjudicated – or even delaying until time runs out on the patents altogether – will cause [it] irreparable harm and unjust hardship." (*Id.* at 9.)

9. Conversely, the defendants propose that staying all discovery is the most efficient and reasonable approach regarding the cases. The defendants base their assertion on the pending appeals, and the fact that the United States Patent and Trademark Office ("PTO") has granted reexamination of three of the four patents at issue in the MDL. According to the defendants, should they succeed on their cross-appeal regarding the validity of the '553 and '681 patents, it would be dispositive of the five new cases that PharmaStem has initiated. (D.I. 23, at 10). The defendants also assert that "any revisions that may be made to the

claims in reexamination would substantially impact the consolidated cases." (*Id.*)

10. After having considered the parties submissions on the issue (D.I. 23, 24, 25), the court concludes that staying all discovery pending a decision by the Federal Circuit, the PTO, or both best serves the interests of justice and is the most efficient approach to the MDL. The decision to stay a case is firmly within the discretion of the court. *See Cost Bros., Inc. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d Cir. 1985). In determining whether a stay is appropriate, the court's discretion is guided by the following factors: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *Xerox Corp. v. 3 Comm Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999) (citing cases); *cf. United Sweetener USA, Inc. v. Nutrasweet Co.*, 766 F. Supp. 212, 217 (D. Del. 1991) (stating a similar test).

11. In the present case, PharmaStem asserts that a stay will prejudice it in that it will be unable to enforce its patents, which have only a few years of exclusivity remaining. The court disagrees. First, PharmaStem's position assumes that the Federal Circuit will decide the pending appeals in its favor, and that the PTO will leave the claims of its three patents unaltered after reexamination. Further, while PharmaStem may suffer some prejudice from a stay, the court is not persuaded that a stay would *unduly* prejudice PharmaStem or present a clear tactical disadvantage. On the other hand, granting the stay will simplify the issues and focus the litigation. For example, if the Federal Circuit determines that PharmaStem's patents are invalid, then many of the issues in the litigation would become moot. A stay, therefore, will conserve the resources of the parties and the court. Lastly, the parties have

not commenced with discovery and no trial date has been set. Thus, the court concludes that the balance of harms weighs in favor of granting the stay.

Therefore, IT IS HEREBY ORDERED that:

1. The defendants' request to stay all discovery pending decisions by the Federal Circuit and the PTO is GRANTED.

2. The parties shall notify the court when the Federal Circuit issues its ruling on the appeal.

3. The parties shall notify the court when the PTO issues its reexamination decision.

Dated: October 6, 2005

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE